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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/927,006	08/09/2001	Dexian Dou		4184

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EXAMINER	
CHISM, BILLY D	
ART UNIT	**PAPER NUMBER**
1654	

DATE MAILED: 03/04/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/927,006	DOU ET AL.	
	Examiner	Art Unit	
	B. Dell Chism	1654	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *22 December 2004*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-8* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-8* is/are rejected.

7)☒ Claim(s) *1 and 3-8* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Withdrawal of Objections and Rejections

The rejections and/or objections made in the prior office action 22 September 2004, which are not explicitly stated below, in original or modified form are withdrawn.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action. Applicants' arguments filed 22 December 2004 will be addressed to the extent that they pertain to the present grounds of rejection.

Claim Objections

1. (Maintained In Part/ New Impart) Claims 1 and 3-8 are objected to because of the following informalities: claim 1 is drawn to a specific amino acid sequence that is not identified with a sequence identifier, e.g., SEQ ID NO: #. Claim 1 is also objected to for comprising matter drawn to nonelected subject matter, i.e., references made to meanings of X, y and n. Claims 3-4, 6 and 8 are objected to for referencing nonelected subject matter, i.e., the phrase "at least one of amino acids" referring to those sequences formally of claim 1. Claim 6 is also objected to for the misspelling of --product-- wherein the term was spelled as "produce". Claims 3, 5 and 7 are objected to because they lack proper introduction, i.e., the present Office practice is to insist that each claim be the object of a sentence starting with a phrase such as "I (or we) claim" or "What is claimed is" or "That which is claimed is". See MPEP 608.01 (m). Appropriate correction is required.

Specification

2. (New) The specification is objected to under 37 CFR 1.821(d) for failing to provide a sequence identifier for each individual sequence. For example, page 4 has described **consensus** sequence(s), which must have a sequence identifier. Correction is required.

Claim Rejections - 35 USC § 102

3. (Maintained) Claims 1-2 and 5-6 rejected under 35 U.S.C. 102(b) as being anticipated by Kundu *et al.* (US Patent 6,210,906 B1)(previously cited). Applicants argue that Kundu *et al.* did not teach the purified or isolated Kringle 5, however, the specification's teachings are contrary to the Applicants' arguments. At column 16, lines 50-56, under the heading of "General Methodologies", Kundu *et al.* teach the isolation of the kringle 5 peptide. It should be noted that the examiner interprets claim 1 of the instant application to read as any purified peptide having anti-angiogenic functionality of the amino acid sequence under consideration. This claim 1 language does not limit the purified peptide to the specific sequence as claimed in the instant claim 1, but merely requires that the functionality of the structure be there. Consequently, that functionality is in the purified Kringle 5 peptide of Kundu *et al.* Thus, since the examiner interpreted the claim 1 language to be open language, Kundu *et al.* anticipates the instantly claimed peptide of claim 1.

4. (Maintained) Claims 1-2 and 5-6 rejected under 35 U.S.C. 102(e) as being anticipated by Kundu *et al.* (US Patent 6,210,906 B1)(previously cited). Applicants argue that Kundu *et al.* did not teach the purified or isolated Kringle 5, however, the specification's teachings are contrary to the Applicants' arguments. At column 16, lines 50-56, under the heading of "General Methodologies", Kundu *et al.* teach the isolation of the kringle 5 peptide. It should be noted that

the examiner interprets claim 1 of the instant application to read as any purified peptide having anti-angiogenic functionality of the amino acid sequence under consideration. This claim 1 language does not limit the purified peptide to the specific sequence as claimed in the instant claim 1, but merely requires that the functionality of the structure be there. Consequently, that functionality is in the purified Kringle 5 peptide of Kundu *et al.* Thus, since the examiner interpreted the claim 1 language to be open language, Kundu *et al.* anticipates the instantly claimed peptide of claim 1.

Claim Rejections - 35 USC § 112

5. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

6. (New) Claims 1-8 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter that was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This is a "written description" rejection, rather than an enablement rejection under 35 U.S.C. 112, first paragraph. Applicant is directed to the Guidelines for the Examination of Patent Applications Under the 35 U.S.C. 112, ¶ 1 "Written Description" Requirement, Federal Register, Vol. 66, No. 4, pages 1099-1111, Friday January 5, 2001.

Vas-Cath Inc. V. Mahurka, 19 USPQ2d 1111, states that "applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in

possession of the invention. The invention, for purposes of the "written description" inquiry, is *whatever is now claimed*" (see page 1117).

A review of the language of the claim indicates that these claims are drawn to a genus, i.e., the genus of polypeptides consisting of derivatives of a peptide having the anti-angiogenic functionality structure of the peptide of claim 1 with D-form amino acid substitutions, other residue substitution, deletions and additions. A description of a genus may be achieved by means of a recitation of a representative number of species falling within the scope of the genus or of a recitation of structural features common to the members of the genus, which features constitute a substantial portion of the genus. *Regents of the University of California v. Eli Lilly & Co.*, 119 F3d 1559, 1569, 43 USPQ2d 1398, 1406 (Fed. Cir. 1997). In *Regents of the University of California v. Eli Lilly* (43 USPQ2d 1398-1412), the court held that a generic statement which defines a genus of nucleic acids by only their functional activity does not provide an adequate written description of the genus. The court indicated that, while applicants are not required to disclose every species encompassed by a genus, the description of the genus is achieved by the recitation of a representative number of species falling within the scope of the claimed genus. At section B(1), the court states "An adequate written description of a DNA ... requires a precise definition, such as by structure, formula, chemical name, or physical properties, not a mere wish or plan for obtaining the claimed chemical invention".

There are relatively few species of the claimed genus disclosed that are within the scope of the claimed genus, *i.e.* the instantly claimed sequence of claim 1 and those other sequences that are specifically disclosed in the specification at pages 4 and 8-9 for example. The disclosure of several species may provide an adequate written description of a genus when the species

disclosed are representative of the genus. However, the present claim encompasses numerous species that are not further described. There is substantial variability among the species.

One of skill in the art would not recognize from the disclosure that the applicant was in possession of the genus of polypeptides comprising of derivatives of a peptide having the anti-angiogenic functionality structure of the peptide of claim 1 with D-form amino acid substitutions, other residue substitution, deletions and additions. The specification does not "clearly allow persons of ordinary skill in the art to recognize that [he or she] invented what is claimed" (see *Vas-Cath* at page 1116). Applicant is reminded that *Vas-Cath* makes clear that the written description provision of 35 U.S.C. 112 is severable from its enablement provision (see page 1115).

7. Claims 1-8 are rejected under 35 U.S.C. 112, **second paragraph**, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

8. (New) Claims 1-8 are vague and indefinite in that the metes and bounds of the term "derived from" are unclear. It is unclear the nature and number of steps required to obtained a "derivative" of the peptides as claimed (cell, tissue, etc.). The term implies a number of different steps that may or may not result in a change in the functional characteristics of the peptide of claim 1 from the source that it is "derived from". Furthermore, it is unclear as to how far derivation can go before the structure and/or functionality of the claimed peptide is no longer efficacious as claimed.

Conclusion

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to B. Dell Chism, whose telephone number is (571) 272-0962. The examiner can normally be reached on M-F 08:30 AM - 5:00 PM. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Bruce Campell, PhD can be reached on (571) 272-0974.

The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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B. Dell Chism 

PATENT EXAMINER